OIPE JC37
APR 29 2003
PATENT & TRADEMARK OFFICE

#9
OM
5/3/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 01-662)

PATENT

In re Application of: Handfield et al.	
Serial No.: 09/995,493	**Before the Examiner: P. Baskar**
Filed: November 28, 2001	**Group Art Unit: 1645**
For: Identification of Actinobacillus Actinomycetemcomitans Antigens For Use in the Diagnosis, Treatment, and Monitoring of Periodontal Diseases	

RECEIVED
MAY 02 2003
TECH CENTER 1600/2900

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313–1450

Sir:

RESPONSE TO OFFICE ACTION MAILED NOVEMBER 27, 2002

Responsive to the Office Action mailed November 27, 2002, Applicants provisionally elect to prosecute claims 15 and 16, designated as Group V by the Examiner. The Action states that the claims of Group V are drawn to a method of detecting an *A. actinomycetemcomitans* infection using an antigen or antibody. Applicants respectfully request modification of the requirement in section 1 of the instant Action, so that Group V is deemed to also include claim 28, as added by Preliminary Amendment on July 2, 2002. A copy of the Preliminary Amendment has been provided for the Examiner's convenience.

Applicants contend that claim 28 properly belongs in Group V, as the restriction requirement defines this group. In addition, Applicants contend that restriction of the claims of Group V and claim 28 would not be proper because the methods of claims 15 and 28 do not constitute independent or distinct inventions. Specifically, Applicants contend that because claim 15 is directed to a method for detecting an *A. actinomycetemcomitans* infection using an antibody that specifically binds an *A. actinomycetemcomitans* polypeptide, and claim 28 is directed to a method for detecting an *A.*

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington D.C. 20231, on April 25, 2003.

Donald L. Zuhn

actinomycetemcomitans infection using a polypeptide (*i.e.*, an *A. actinomycetemcomitans* antigen) that specifically binds an anti-*A. actinomycetemcomitans* antibody, both claim 15 and claim 28 are drawn to methods of detecting an *A. actinomycetemcomitans* infection using an antigen or antibody. Because the methods of claims 15 and 28 do not constitute independent or distinct inventions, Applicants respectfully request that the Examiner find that Group V includes the methods of claims 15, 16, and 28.

In order to comply with 37 C.F.R. § 1.143, Applicants also provisionally elect to prosecute the claims of Group V as they relate to the amino acid sequence of SEQ ID NO: 52. The Action states that the sequences of SEQ ID NOs: 1-224 constitute independent and distinct inventions because these sequences represent structurally different polypeptides and the polynucleotides encoding them, and therefore, would have different effects. Applicants respectfully request modification of the requirement in section 3 of the instant Action, so that Applicants might be permitted to elect to prosecute the claims of Group V as they relate to a polypeptide comprising at least five contiguous amino acids of the amino acid sequence set forth in SEQ ID NO: 226, SEQ ID NO: 228, SEQ ID NO: 230, SEQ ID NO: 232, or SEQ ID NO: 234. In addition, Applicants respectfully request reconsideration of the requirement in section 3 of the instant Action, so that Applicants might be permitted to elect to prosecute the claims of Group V as they relate to a polypeptide comprising at least five contiguous amino acids of the amino acid sequence set forth in *any* of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, . . . or SEQ ID NO: 234.

In support of Applicants' request for reconsideration of the requirement in section 3 of the instant Action, Applicants contend that polypeptides comprising at least five contiguous amino acids of the amino acid sequence set forth in *any* of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, . . . or SEQ ID NO: 234 would not – in the context of the claims of Group V – be incapable of use together, or possess different modes of operation, different functions, or different effects. Applicants note that the instant application teaches that *in vivo* induced antigen technology (IVIAT) was used to identify sequences that are specifically expressed in *A. actinomycetemcomitans* when that organism is actually causing disease in animals, as opposed to sequences that are expressed when *A. actinomycetemcomitans* is merely cultured in the laboratory, and environmental signals that normally cause *A. actinomycetemcomitans* to express virulence genes are missing (page 9, lines 14-20). The

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

instant application also teaches that sequences identified in this manner are useful in diagnostic tests to identify individuals who are infected with *A. actinomycetemcomitans* (page 9, lines 20-22).

Applicants contend that in view of the specification's teachings, the diagnostic methods of Group V could be readily practiced using more than one polypeptide comprising at least five contiguous amino acids of the amino acid sequence set forth in *any* of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, . . . or SEQ ID NO: 234 (or more than one antibody recognizing more than one polypeptide), and that by using more than one polypeptide or antibody, the reliability of such diagnostic methods might very well increase. Applicants, therefore, contend that in the context of the claims of Group V, polypeptides comprising at least five contiguous amino acids of the amino acid sequence set forth in *any* of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, . . . or SEQ ID NO: 234 (or antibodies recognizing more than one polypeptide) would not be incapable of use together. Similarly, Applicants contend that in the context of the claims of Group V, polypeptides comprising at least five contiguous amino acids of the amino acid sequence set forth in *any* of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, . . . or SEQ ID NO: 234 (or antibodies recognizing more than one polypeptide) would not possess different modes of operation, different functions, or different effects. In fact, in the context of the claims of Group V, such polypeptides or antibodies serve the same function: to identify individuals infected with *A. actinomycetemcomitans*. Because polypeptides comprising at least five contiguous amino acids of the amino acid sequence set forth in *any* of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, . . . or SEQ ID NO: 234 would not – in the context of the claims of Group V – be incapable of use together, or possess different modes of operation, different functions, or different effects, Applicants respectfully request that the requirement in section 3 of the instant Action be withdrawn.

Moreover, Applicants respectfully submit that there will be no undue hardship on the Office in performing a search throughout the full scope of the claims of Group V were the requirement in section 3 of the instant Action withdrawn. As the instant Action states, the invention of Group V is a method of detecting an *A. actinomycetemcomitans* infection using an antigen or antibody. The invention of Group V, therefore, is not a polypeptide or an antibody.

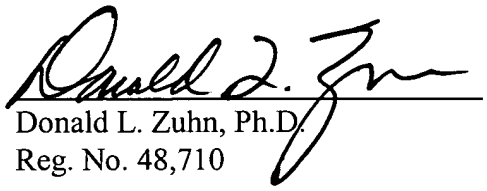
Applicants enclose a petition for a four-month extension of time. The Commissioner is authorized to charge any deficiency to Deposit Account No. 13-2490. If Examiner Baskar believes it

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

to be helpful, the Examiner is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff

Dated: April 25, 2003

By: 
Donald L. Zuhn, Ph.D.
Reg. No. 48,710

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001